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| 09/878,922 | 06/13/2001 | Randall S. Hickie | 82021-0012 | 2867 |
| 24633 | 7590 | 02/23/2006 | EXAMINER | |
| HOGAN & HARTSON LLP IP GROUP, COLUMBIA SQUARE 555 THIRTEENTH STREET, N.W. WASHINGTON, DC 20004 | | | EREZO, DARWIN P | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 3731 | |

DATE MAILED: 02/23/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/878,922

Applicant(s)

HICKLE ET AL.

Examiner

Darwin P. Erez

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 November 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5, 10-14, 16-66 and 80-128 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-5, 10-14, 16-56, 64-66, 80-115 and 128 is/are allowed.
- 6) ☒ Claim(s) 57-63, 116-120, 126 and 127 is/are rejected.
- 7) ☒ Claim(s) 121-125 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 117-119 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 117 is amended with limitations cancelled that renders the claim vague and indefinite. The claim now recites "around the base of each to diffuse". It is unclear as to what base is being referred to.

Claim 119 recites "nostril portions. nare prongs". The claim does not clearly set forth the metes and bounds of the patent protection desired.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 57, 58, 62, 63, 116, 120, 126 and 127 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,422,240 to Levitsky et al. in view of US 6,439,234 to Curti et al.

Levitsky teaches a method for delivering an inspired gas to a person and monitoring expired gases from the person, the method comprising interfacing an

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oronasal device having fluid inlets that inserted into the patient's nares **78** and an area around the patient's mouth **80**; delivering a flow of inhalation gas to the patient via a plurality of fluid outlet holes **88** being located immediately about a base of and partially surrounding each portions extending toward the nares (as seen in Fig. 6a, the holes **88** are at least partially surrounding the fluid inlets **78**); and monitoring the expired gas stream with an analyzer (col. 7, line 46). Levitsky also teaches the nostril portions include a distal end and proximal end, the distal end having openings to the fluid inlets; and wherein the fluid outlet holes are located downstream from the fluid inlets;

Levitsky is silent with regards to the steps of determining whether the person is in inhalation or exhalation phase and delivering an increased flow of inspired gas to the person during the inhalation phase.

Curti also teaches a method of supplying gas to a person and sampling expired gas from the person, the method comprising the steps of using a nasal cannula to detect when a person is inhaling or exhaling and delivering an increase flow of gas to the person during the inhalation phase (col. 3, lines 11-24). The incorporated US 5,626,131 reference teaches a method of intermittent gas insufflation, which teaches detecting the respiratory phase of a user.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to add the method step of detecting when a person is inhaling or exhaling and delivering an increased flow of gas to the person during the inhalation phase, as disclosed by Curti, in the method taught by Levitsky because delivering gas only during the inhalation phase prevents diluting the expired gas needed

for sampling (Curti; col. 2, lines 38-52). It would also be inherent that the gas delivered during the exhalation would be a lower flow than the increased flow of gas during inhalation. Furthermore, since the modified device would be used to determine the respiratory phase of a user, then it would be inherent that the breath rate of the user is monitored.

5. Claims 59 are rejected under 35 U.S.C. 103(a) as being unpatentable over Levitsky et al. in view of Curti et al. and in view of US 5,535,739 to Rapaport et al.

Levitsky/Curti fails to teach the method of determining whether the person is inhaling and exhaling comprising the step of analyzing the pressure waveform. However, Rapaport teaches an oxygen delivery system comprising a nasal cannula and monitoring a pressure waveform from the cannula (col. 14, lines 38-53). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Levitsky/Curti and include the step of determining the respiratory phase by analyzing a pressure waveform since it is known in the CPAP art to monitor a respiratory phase of a patient via CO₂ content, pressure waveform, humidity, etc. Therefore, choosing a particular method of analyzing would be a mere design choice to one of ordinary skill in the art.

6. Claims 60 and 61 are rejected under 35 U.S.C. 103(a) as being unpatentable over Levitsky et al. in view of Curti et al. and in view of US 6,467,477 to Frank et al.

Levitsky/Curti fails to teach the method of determining whether the person is inhaling and exhaling comprising the step of analyzing pressuring the person's gas stream using a humidity or temperature sensor. Frank teaches an oxygen delivery

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system comprising a humidity or temperature sensor for detecting whether the person is inhaling or exhaling and monitors the respiratory rate of the person at the respiratory site (col. 7, lines 19-24). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use the delivery system of Frank in the method steps taught by Levitsky/Curti because it allows the person to control the delivery device using different sensors and different parameters.

7. Claims 117-119 are rejected under 35 U.S.C. 103(a) as being unpatentable over Levitsky et al. in view of Curti et al. and in view of US 5,046,491 to Derrick.

Levitsky/Curti is silent with regards to the fluid outlet holes being arranged in an a concentric arc. Instead, Levitsky teaches a straight tube with fluid outlet holes. However, Derrick teaches a similar nasal cannula, in which the fluid outlet holes are arranged in a concentric arc (Fig. 1 and 2). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Levitsky/Curti and have the fluid outlet holes arranged in a concentric arc because it would allow the inhalation gas to be delivered over a greater surface area.

Allowable Subject Matter

8. Claims 1-5, 10-14, 16-56, 64-66, 80-115 and 128 are allowed.

9. Claims 121-125 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Response to Arguments

10. Applicant's arguments filed 11/28/05 have been fully considered but they are not persuasive.

11. The applicant argues that Levitsky fails to teach the fluid outlet holes being about a base and partially surrounding each portions extending to the nares. However, as stated in the rejection above, the fluid outlet holes do indeed partially surround the nare portions. The applicant has not provided any other structural limitation to clearly define over the prior art.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Darwin P. Erez who's telephone number is (571) 272-4695. The examiner can normally be reached on M-F (7:30-4:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan T. Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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GLENN K. DAWSON
PRIMARY EXAMINER